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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,818	10/02/2003	Klaus Dittmann	WWELL73.006C1	9797

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EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1617	
NOTIFICATION DATE	DELIVERY MODE
03/30/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)
	10/677,818	DITTMANN ET AL.
	Examiner	**Art Unit**
	ALI SOROUSH	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2010*.
2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-17 and 21-23* is/are pending in the application.
  4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *13-17 and 21-23* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *05 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
  Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/02/2010 has been entered.

Claim Status

Claims 13-17 and 21-23 are pending.

Claims 1-12 and 18-20 are cancelled.

Claims 13 and 21 are currently amended.

Claims 13-17 and 21-23 have been examined.

Claims 13-17 and 21-23 are rejected.

Priority

Priority to CON PCT/EP02/03403 filed on 03/27/2002 which claims priority to German Patent Application 10117834.4 filed on 04/03/2001 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

This is a new ground of rejection.

Claims 15-17 recite the limitation "said biological material" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 13, 14, 17, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mishra et al. (O-Phospho-L-tyrosine Inhibits Cellular Growth by Activating Protein Tyrosine Phosphatases, Published 02/01/1993).

The claims are directed to a method of selectively protecting non-transformed biological cells over transformed biological cells from cell-damaging factors comprising: providing a human or animal with phosphotyrosine.

Mishra et al. teach, “O-Phospho-L-tyrosine(P-Tyr) … inhibited growth of human renal and breast canrcinoma cells.” (See abstract). “P-Tyr was shown to inhibit the growth of human breast and renal carcinoma cells and inhibit EGF receptor tyrosine phosphorylation.” (See page 557, Column 2, Lines 17-19). “P-Tyr sensitized the ACHN cells to the cytostatic effect of doxorubicin and VP-16. The biological effects of the tyrosine analogue P-Tyr highlights its potential role as an anticancer agent.” (See page 562, Column 2, Lines 41-42). “The combination regimen resulted in complete inhibition of growth of ACHN cells." (See page 562, Column 2, Lines 22-23).

Mishra et al. lacks a teaching wherein P-Tyr is provided to a human or animal.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide P-Tyr a chemotherapeutic agent to a patient with renal and/or breast cancer, since Mishra et al. teach that P-Tyr has a potential role as an anticancer agent. A human patient with renal and/or breast cancer have cells that are both transformed and non-transformed. Further, administration of P-Tyr to patients with renal and/or breast carcinoma would inherently result in the selective protection of non-transformed cells.

Response to Applicant's Arguments

Applicant argues that Mishra et al. do not teach nor suggest non-transformed cells would be selectively protected from cell damage. Further, Applicant argues that such a protective function does not meet the criteria of inherency since Mishra et al. does not apply phosphotyrosine to non-transformed cells but only to cancer cells. Applicant's argument has been fully considered but found not to be persuasive. The selective protective activity of phosphotyrosine is an inherent property of the compound and its properties are inseparable (In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). The introductory language of a claim drawn to a process of using the composition does not constitute a new use since the old composition possessed the property and Applicants merely discovered this property (In re Tomlison, 363 F.2d 928, 150 USPQ 623 (CCPA 1966)). Claims are unpatentable where the prior art process per se of applying the chemical is the same, notwithstanding Applicant's different purpose for application of the compound (In re Kirby, 40 USPQ 368). The instant method steps and the method steps of the prior art (Mishra et al.) are identical when applied to a patient, which is the obvious intent of the teachings of Mishra et al. Since, a human patient with cancer possess both transformed and non-transformed cells, it would necessarily follow that application of phosphotyrosine would result in the selective protection of non-transformed cells, as this is a property of the compound. The mere discovery of this property is not patentable. Therefore, the rejection is maintained.

2. Claims 13-17 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blomqvist et al. (The combination of radiotherapy, adjuvant chemotherapy (cyclophosphamide-doxorubicin-ftorafur) and tamoxifen in stage II breast cancer. Long term follow-up results of a randomized trial, Published 1992) further in view Mishra et al. (O-Phospho-L-tyrosine Inhibits Cellular Growth by Activating Protein Tyrosine Phosphatases, Published 02/01/1993).

The claims are directed to a method of selectively protecting non-transformed biological cells over transformed biological cells from cell-damaging factors comprising: providing a human or animal with phosphotyrosine.

Blomqvist et al. teach that a combination of chemotherapy(cyclophosphamide-doxorubicin-ftorafur) and radiotherapy gave better local control of stage II breast cancer compared to either treatment alone.

Blomqvist et al. lacks a teaching wherein P-Tyr is administered to the biological matyterial.

Mishra et al. teach, “O-Phospho-L-tyrosine(P-Tyr) … inhibited growth of human renal and breast canrcinoma cells.” (See abstract). “P-Tyr was shown to inhibit the growth of human breast and renal carcinoma cells and inhibit EGF receptor tyrosine phosphorylation.” (See page 557, Column 2, Lines 17-19). “P-Tyr sensitized the ACHN cells to the cytostatic effect of doxorubicin and VP-16. The biological effects of the tyrosine analogue P-Tyr highlights its potential role as an anticancer agent." (See page 562, Column 2, Lines 41-42). "The combination regimen resulted in complete inhibition of growth of ACHN cells." (See page 562, Column 2, Lines 22-23).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Blomqvist et al. with Mishra et al. One would have been motivated to administer P-Tyr as a chemotherapeutic agent to the patients of Blomqvist et al. since the addition of P-Tyr would provide the additive effect of treating breast carcinoma. A human patient with breast cancer have cells that are both transformed and non-transformed. Further, the administration of P-Tyr to patients with renal and/or breast carcinoma would inherently result in the selective protection of non-transformed cells.

Response to Applicant's Arguments

Applicant argues that the alleged deficiencies of Mishra et al. are not cured. Applicant's argument has been fully considered but found not to be persuasive. The Examiner has shown above that the alleged deficiencies of Mishra et al. are a property of the phosphotyrosine compound and does not make the instant claims patentable. Furthermore, an appreciation of the problem identified and solved by Applicant is not, standing alone, conclusive evidence of the nonobviousness of the claimed subject matter. The references may suggest doing what Applicant has done even though workers in the art were ignorant of the existence of the problem. Therefore the rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALI SOROUSH whose telephone number is (571)272-9925. The examiner can normally be reached on M-F (9am-6pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi can be reached on (571)272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 1617

March 23, 2011